

Office of Technical Assistance Research Proposal
***Elimination of Certain Phthalates From Products/Processes
that Pose Exposure Risk to the General Population***

PROBLEM OUTLINE

The health and environmental impacts of phthalates have been a subject of controversy in recent years. Certain phthalates have been linked to cancer, organ damage (kidneys, liver, and testicles), and reproductive toxicity effects in animals. Experiments have indicated that low exposure of animals to certain phthalates during a precise window of vulnerability¹ can grossly alter the reproductive organs and functions in males^{2,3}. A number of studies indicate potential endocrine disrupting effects of certain phthalate esters in general and in human reproductive organs⁴.

Phthalates are used in a variety of products⁵. Some studies have indicated that phthalates have been present in unexpected materials such as dry infant formulas⁶. When used in certain products, such as baby toys and medical devices, phthalates can leach into the human body.

It is believed that the adverse effects of these phthalates may be additive⁷. Recent studies have indicated a much higher human exposure to these phthalates than previously perceived^{2,8,9}. Although it is not still known what level of exposure causes illness, a relative comparison of the recently established levels of human exposure with the levels that have caused developmental effects in animal studies has raised concern.

The level of exposure to individual phthalates of concern does not seem to follow the level of production of these phthalates^{8,9,10}. This suggests that phthalates that are produced in lower volumes and are present in products other than soft plastics are also significant when evaluating and addressing exposure risk. Although many questions regarding phthalate toxicity and its sources of exposure have not been answered, it is reasonable to take action to reduce the risk of exposure of the general public, especially that of the unborn and the young, to this class of chemicals.

Worldwide, there has been an effort to eliminate phthalates that are considered potential endocrine disrupters from certain products. The European Union has banned six toxic phthalates found in soft PVC toys marketed for teething. The federal Consumer Product Safety Commission has asked for voluntary removal of phthalates in teething toys and rattles. Mattel, a world leading toy manufacturer, has decided to remove PVC from its toys and switch to plant-based plastics¹¹. Several other global companies have decided to replace PVC in their products¹².

Labeling of phthalates in some products may become a requirement by certain regulatory agencies at some point in time. Such a requirement would add an additional incentive for the reformulation of products containing phthalates. Some companies have already taken this factor into consideration.

Eliminating a particular phthalate in a product may be more complicated than simply finding an alternative chemical that provides seemingly the same function as the phthalate in the product. For example, it has been reported that di (2-ethylhexyl) phthalate (DEHP), which is used in medical plastics for blood storage, has the unintended but beneficial effect of extending the shelf life and functional quality of the blood. The mechanisms by which DEHP leads to these functions are unknown. Consequently, the newly developed alternative plastics for blood storage have not yet found any buyers².

Phthalate-free medical plastics are currently commercialized and used in functions other than blood storage. A few manufacturers have used soybean oil as an alternative plasticizer. Certain citrates and adipates have also been used as a substitute for phthalate plasticizers in some soft PVC products.

Current annual worldwide production of phthalates is estimated at one billion pounds. Table (1) shows phthalate usage in Massachusetts as reported in the 1999 Toxics Use Reduction (TURA) database.

PHTHALATE	BUTYL BENZYL PHTHALATE (BBP) 85-68-7	DI (2-ETHYLHEXYL) PHTHALATE (DEHP) 117-81-7	DIETHYL PHTHALATE (DEP) 84-66-2	DI-N--BUTYL PHTHALATE (DBP) 84-74-2	DI-N-OCTYL PHTHALATE 117-84-0	TOTAL
USAGE	104,042	5,138,427	54,382	435,595	435,600	6,168,046

Table 1. Phthalate Usage in Massachusetts. Information compiled from TURA data for 1999.

RESEARCH OBJECTIVES AND SCOPE

This project focuses on eliminating phthalates in soft plastics, consumer products, and other products/processes that are deemed to be a source of exposure to phthalates in the general population. Phthalate elimination may be achieved through substitution of alternative chemicals for the phthalate, developing new chemistries that provide the same functions, or development of new materials that can be substituted for the original products' building material. The alternative chemistries/products should have no known endocrine-disruption or other serious health and safety or environmental effects.

The same criteria used for the evaluation of a particular phthalate should be used in evaluating its alternative(s). A complete evaluation of the relevant physical and chemical properties and specifications of the product would be necessary when comparisons are made between the phthalate containing product and the alternative.

OTA can assist in finding an industry partner for this project. ■

¹ This period in test animals corresponds to the end of a woman's first trimester of pregnancy.

² Janet Raloff, "New concerns about Phthalates," Science News, September 2, 2000

³ According to L. Earl Gray Jr., a phthalate toxicologist with EPA, the reproductive toxicity of phthalates depends on their molecular shape. Phthalates are ring-shaped molecules with two ester side-chains. Phthalates that disrupt early (fetal) testosterone production tend to carry relatively short esters on the same side of the ring. Gray notes that moving one of the esters to the opposite side of the ring causes the compound to lose its developmental toxicity. (See Endnote 2.)

⁴ For example see 1) Susan Jobling, et al., "A Variety of Environmentally Persistent Chemicals, Including Some Phthalate Plasticizers, Are Weakly Estrogenic," Environmental Health Perspectives [the NIEHS Journal], 103: 582-587 (1995); and 2) Ivelisse Colón, et al., "Identification Of Phthalate Esters In The Serum Of Young Puerto Rican Girls With Premature Breast Development," Environmental Health Perspectives, 108:895-900 (2000), [Online 8 August 2000]. Also see Endnote 2.

⁵ Such as solvent for dyes, adhesives, wires and cables, tool handles, cosmetics, personal care products, plastic food wraps, and soft plastics used in toys and medical devices. For a list of phthalates and the products in which they are found see for example http://seattletimes.nwsources.com/news/nation-world/html98/s1chem26_20000826.html.

⁶ INFAC Canada Newsletter Article, "Toxic Phthalates in Infant Formulas," [Online Spring 1996], <http://www.infactcanada.ca/newsletters/spring96/phthalat.htm>.

⁷ According to L. Earl Gray Jr., a phthalate toxicologist with EPA. See Endnote 2 for reference.

⁸ CDC Press Release, "Study Demonstrates Exposure of People to Phthalates," www.cdc.gov/od/oc/media/pressrel/rsk0901.htm.

⁹ Benjamin C. Blount, Manori J. Silva, Samuel P. Caudill, Larry L. Needham, Jim L. Pirkle, Eric J. Sampson, George W. Lucier, Richard J. Jackson, and John W. Brock, “*Levels of Seven Urinary Phthalate Metabolites in a Human Reference Population*,” Environmental Health Perspectives, 108:979-982 (2000)[Online 1 September 2000].

¹⁰ Phthalates that had higher levels of metabolites in human urine are used in detergents, lubricating oils, solvents, and a wide variety of other products including cosmetics and wood finishes. The commercial production of these phthalates is not the highest. There are other phthalates that are produced in larger quantities but whose metabolites in urine samples were lower than the above group. These phthalates are used primarily as plasticizers in flexible polyvinyl chloride products (PVCs) such as blood bags, food packaging, and children’s toys. Di (2-ethylhexyl) phthalate (DEHP) is the primary phthalate in this group.

¹¹ Such toys will be available in 2001.

¹² <http://www.greenpeac.org/pressreleases/toxics/1999dec82.html>.